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09/618,307	07/18/2000	Clements C. Lambeth	WEYE115226	9512

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EXAMINER	
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ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 January 2004 has been entered. Claim 27 has been amended, and new claims 29-31 have been added. Claims 20-31 are pending and examined.

Applicant is hereby notified that the references appended to the amendment of 30 January 2004 as Attachments A-G have either not been received by the Office, or were received but were not scanned into the Image File Wrapper. Due to time constraints, the Examiner was unable to notify Applicant of this problem prior to the issuance of the instant Office action. Where possible, the Examiner reviewed the cited references which had been previously submitted by Applicant. Applicant is invited to submit the missing references with their response to the instant Office action. Applicant is also requested to list these references on an Information Disclosure Statement. The error is regretted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 30 January 2004 has obviated the rejection of claim 27 under 35 USC 112, second paragraph.

Claims 20-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 2 of the last Office action for claims 20-28.

Claims 20-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on page 3 of the last Office action for claims 20-28.

Claims 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bridgwater in view of El-Kassay et al and Stoehr et al (1998), as stated on page 3 of the last Office action for claims 20-28.

No claim is allowed.

Applicant's arguments filed 30 January 2004 have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the failure of the claims to be directed to DNA sequences *per se*, the high level of skill in the art, the guidance in the specification regarding the isolation of DNA from various plant species as also taught by Qiagen (Attachment A), and the knowledge by those skilled in the art of methods of DNA analysis as taught by Staub et al (1996) (Attachment B).

The Examiner maintains that methods of using products such as DNA sequences in the form of molecular markers, wherein said products are inadequately described, are

properly subjected to a rejection under 35 USC 112, first paragraph, as lacking an adequate written description. As stated previously, the disclosure of SSR markers from a single pine species is not representative of the broadly claimed genus of any type of molecular markers from any taxonomically divergent tree species.

See *University of Rochester v. G.D. Searle & Co., Inc.,* U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L, decided 05 March 2003, at page 18, bottom paragraph, which teaches that method claims are properly subjected to a written description rejection if the starting material which requires that method is itself inadequately described.

Regarding the level of skill in the art, the Examiner maintains that Applicant's mere assertions are not probative. As stated previously, and as admitted by Applicant, the claims are not merely drawn to methods of isolating DNA or molecular markers from various tree species. Instead, the claims are drawn to a method for tree breeding comprising determining the pedigree of trees using DNA analysis. The level of skill is low regarding said pedigree analysis and tree breeding methods involving it, as discussed previously. Qiagen was not found by the Examiner, but Staub et al (1996), previously submitted by Applicant, is silent with respect to said pedigree analysis or tree breeding methods. Staub et al mentions the application of molecular markers to the determination of linkage groups and genetic maps, but not pedigree analysis. Furthermore, Staub et al supports the Examiner's position, in its teaching that marker-assisted selection is still in its infancy, and is hampered by genetic interactions such as

epistasis, loose linkages, and problems in accurate phenotypic classification (see, e.g., page 737, column 3, bottom two paragraphs).

Applicant urges that the enablement rejection is improper, given the disclosure in the specification of various methods for isolating DNA markers from a variety of tree species, as also taught by Staub et al (1996); the assertions in the specification that the claimed breeding technique involving molecular pedigree analysis can be applied to any tree species, the exemplification of a single type of marker (SSR) in a single tree species (*Pinus taeda* or Loblolly pine); the ability of the exemplified primer pairs to isolate markers in another *Pinus* species or in 110 other conifer species as taught by Anzidei et al; the knowledge by those skilled in the art of other DNA markers in other tree species, as illustrated by various references; the guidance in the specification regarding the determination of phenotype; the failure of the references cited by the Examiner to provide a reason to doubt the truth of the assertions in the specification as required by *Marzocchi*; and the correlation between the claim breadth, guidance in the specification, and predictability in the art.

The Examiner maintains that the mere isolation of DNA markers is not the issue, and that Staub et al supports the Examiner's position regarding the general unpredictability inherent in the process, as stated above. Regarding the references cited by Applicant, the Examiner regrets that he was unable to evaluate Anzidei et al, Krauss et al or Nicese et al. The Examiner has reexamined Stoehr et al, Cervera et al, and Isagi et al, and maintains his position that the mere availability of molecular markers is not the only issue. The Examiner further maintains that the specification, and not the

prior art, should teach the essential elements of Applicant's invention, as taught by *Genentech* cited previously.

Furthermore, Cervera et al only provide conclusive evidence in linking a single AFLP marker to a single disease resistance locus (see, e.g., page 49, Figure 1). All other applications of AFLP markers, including pedigree analysis, are prophetic. Staub et al (1996) reinforce the idea that disease resistance genes lend themselves particularly well to molecular marker analysis (see, e.g., page 737, column 3, first full paragraph); however, the instant claims encompass much more than this concept. Isagi et al and Stoeher et al rely upon microsattelite (or SSR) markers, the same type of DNA markers as utilized by Applicant, and so do not provide a teaching of other non-exemplified marker types.

Regarding the ability of the exemplified primer pairs to isolate markers from non-*Pinus* genera, the Examiner was unable to evaluate the Anzidei et al reference alleged to teach this concept. However, it is noted that the exemplified primer pairs comprised highly conserved chloroplast DNA, while the claims are not limited to chloroplast DNA-derived molecular markers.

Regarding Applicant's assertions that the claimed process is predictable and that the exemplification of a single type of molecular marker from a single pine species is sufficient to enable the broadly claimed process, the Examiner maintains that the art cited by the Examiner indeed supports his position that the process is not predictable, and that the exemplified pine species has unique characteristics which make it uniquely suited to the claimed process. Furthermore, Staub et al (1996) teach that phenotypic

evaluation is not predictable (see, e.g., page 729, column 2, first full paragraph; paragraph bridging pages 736 and 737; page 737, column 2, first full paragraph).

Regarding Lambeth et al and White cited by the Examiner, the Examiner maintains that the references demonstrate the unpredictability inherent in the process. White teaches that open pollination in tropical tree species, encompassed by the instant claims, is unpredictable. Applicant's assertion does not refute the facts provided by the reference. Lambeth et al teach that some failure was observed when utilizing the exemplified pine species and SSR markers, thus supporting the Examiner's position that the process is unpredictable even for the exemplified tree species and markers, let alone non-exemplified tree species and marker types. Furthermore, Lambeth et al admit that the success observed by them was dependent upon a particular breeding population and a small number of markers (see, e.g., page 930, sentence bridging columns 1 and 2 of the Abstract, and column 2 of the Abstract).

Applicant urges that the obviousness rejection is improper, given the lack of a suggestion to combine the cited references and the teaching away of the cited references from the claimed process. The Examiner disagrees with Applicant's interpretation of the cited references, and reiterates his position that explicit suggestions to combine their teachings may be found in the references. The Examiner also reiterates his position that the scope of the claims is not commensurate with Applicant's arguments of unexpected results, per *Lindner* and *Grasselli.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

April 14, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638